In the claims:

1. (Currently Amended) A method for solubilizing and recovering, in bioactive form ~~and isolated form~~, a target polypeptide from a host organism in which the target polypeptide is present in insoluble form, which comprises:

disrupting the host cell to produce a lysate;

recovering lysate precipitate containing the target polypeptide;

~~resuspending~~ solubilizing the lysate precipitate in a denaturant-free, non-buffered solubilization solution ~~to~~ produceing a solubilization preparation that comprises 1) a concentration of sodium hydroxide ~~between~~ about 8 and about 10 mM and 2) a concentration of polypeptide ~~between~~ about 1 and about 4mg polypeptide per ml solubilization solution, wherein the resultant solubiization preparation has a pH of ~~between~~ about 9 and about 11.2~~; and recovering supernatant from the solubilization preparation containing bioactive target peptide~~.

2. (Currently Amended) The method of claim 1, wherein the solubilization solution is ~~substantially~~ free of denaturants and detergents.

3. (Currently Amended) The method of claim 1, further comprising the step of purifying ~~formulating~~ the bioactive target polypeptide.

4. (Currently Amended) The method of claim 1, where the solubilization preparation has a pH ~~between~~ about ~~9.0~~ 10.5 ~~and~~ to about 11.2

5. (Currently Amended) The method of claim 1, wherein the solubilization preparation comprises ~~a concentration of~~ sodium hydroxide ~~between~~ about ~~8.5~~ 0 ~~and~~ to about ~~9.5~~ 10 mM.

6. (Currently Amended) The method of claim 1, wherein the solubilization preparation comprises a concentration of polypeptide ~~between~~ about ~~2.5~~ 1.0 ~~and~~ to about ~~3~~ 4 mg polypeptide per ml of solubilization solution.

7. (Original) The method of claim 1, wherein the solubilization solution further comprises a stabilizing compound.

8. (Currently Amended) The method of claim 7, wherein the stabilizing compound is at concentration between about 1 ~~and~~ to about 20 mM.

9. (Original) The method of claim 7, wherein the solubilization solution further comprises a second stabilizing compound.

10. (Original) The method of claim 7, wherein the stabilizing compound is a stabilizing sugar, stabilizing polyol, stabilizing amino acid or stabilizing polymer.

11. (Currently Amended) The method of claim 10, wherein the stabilizing polyol is mannitol and the stabilizing sugar is lactose.

12. (Original) The method of claim 7, wherein the host organism is bacteria or yeast.

13. (Currently Amended) The method of claim 1, wherein the host is an Escherichia coli cell ~~or a Bacillus thuringiensis cell~~.

14. (Currently Amended) The method of claim 13, wherein the host cell is a Yeast ~~Saccharomyces~~ cell.

15. (Original) The method of claim 1, wherein the target polypeptide is present within the host organism in inclusion bodies

16. (Currently Amended) The method of claim 1, wherein the target polypeptide is ~~troponin~~ a protein or a subunit of ~~troponin~~ the protein.

17. (Currently Amended) The ~~A protein produced by the~~ method of claim 1 wherein said target polypeptide is a protein.

18. (Currently Amended) The ~~Troponin produced by the~~ method of claim 16 wherein said target polypeptide is troponin.

19. (Original) The ~~Troponin I produced by the~~ method of claim 16 wherein said target polypeptide is troponin I.

20. (Currently Amended) A method for formulating a target bioactive polypeptide into a pharmaceutically acceptable form , comprising:
(i) dialyzing or ultrafiltering-diafiltering the target biotactive polypeptide into an aqueous stabilization buffer ~~comprising~~ containing a buffering salt and stabilizing compounds
~~(ii) dispensing the target peptide into vials.~~

21. (Currently Amended) The method of claim 20, wherein the target ~~peptide~~ protein to be formulated is troponin.

22. (Currently Amended) The method of claim 20, wherein the stabilization ~~buffer comprises~~ solution contains a buffer salt at concentration ~~between~~ about 5 ~~and~~ to 40 mM.

23. (Currently Amended) The method of claim 20, wherein the stabilizing compound in the formulation solution is a sugar or polyol

24. (Currently Amended) The method of claim 20, wherein the stabilizing compound in the formulation solution is a sugar at concentration ~~between~~ about 2 to about 12 mM.

25. (Currently Amended) The method of claim 20, wherein the stabilizing compound in the formulation solution is a polyol at concentration ~~between~~ about 5 to about 100 mM.

26. (Currently Amended) A method for solubilizing and recovering, in bioactive and isolated form a target polypeptide from a host organism in which the target polypeptide is present in insoluble form, which comprises:

(a) disrupting the host cell to produce a lysate;

~~(b) precipitating said lysate~~

(~~c~~ b) recovering a ~~the lysate~~ precipitate containing the target polypeptide from the lysate;

(~~d~~ c) solubilizing ~~resuspending~~ the ~~lysate~~ precipitate in a denaturant-free non-buffered solubilization solution to produce a solubilization preparation that comprises

1) hydrogen chloride between 10 and 20 mM; and

2) bioactive target polypeptide between 1 and 4 mg ~~precipitate~~ per ml solubilization solution, and

3) pH between 2.0 and 3.0~~; and~~

~~(d) recovering bioactive the target peptide as supernatant from the solubilization preparation of (c)~~ .

27. (Original) The method of claim 26, further comprising adjusting the pH of the supernatant to pH 9.5 with NaOH.

28. (Currently Amended) The method of claim 26, wherein the solubilization solution is free of denaturants and detergents.

29. (Currently Amended) The method of claim 26, wherein the solubilization preparation has a pH ~~between~~ about 2.2 ~~and~~ to about 2.8.

30. (Currently Amended) The method of claim 26, wherein the solubilization preparation comprises a concentration of hydrogen chloride ~~between~~ about 10 ~~and~~ to about 20 mM.

31. (Currently Amended) The method of claim 26, wherein the solubilization preparation comprises a concentration of polypeptide ~~between~~ about 2.5 ~~and~~ to about 3 mg polypeptide per ml solubilization solution.

32. (Currently Amended) The method of claim 26, wherein the solubilization preparation comprises a concentration of polypeptide ~~between~~ about 1.8 ~~and~~ to about 2 mg polypeptide per ml solubilization solution.

33. (Original) The method of claim 26, wherein the solubilization solution further comprises a stabilizing compound.

34. (Currently Amended) The method of claim 33, wherein the stabilizing compound is at concentration ~~between~~ about 1 ~~and~~ to about 20 mM.

35. (Original) The method of claim 33, wherein the solubilization solution further comprises a second stabilizing compound.

36. (Original) The method of claim 33, wherein the stabilizing compound is a sugar, polyol, amino acid or polymer.

37. (Original) The method of claim 33, wherein the stabilizing compound is mannitol and lactose.

38. (Original) The method of claim 26, wherein the host cell is bacteria or yeast.

39. (Currently Amended) The method of claim 38, wherein the host cell is an Escherichia coli cell ~~or a Bacillus thuringiensis cell~~.

40. (Original) The method of claim 38, wherein the host cell is a Saccharomyces cell.

41. (Original) The method of claim 38, wherein the heterologous polypeptide is present within inclusion bodies within the host cell.

42. (Currently Amended) A method for isolating recombinant polypeptides comprising:

providing a non-buffered solution containing a stabilizing compound and hydrogen chloride between 10 and 20 mM;

producing a ~~protein~~ polypeptide solution about 1 to about 4 mg polypeptide per ml by adding to the non-buffered denaturant free solution an insoluble recombinant polypeptide, ~~between about 1 and about 4mg polypeptide per ml non-buffered solution~~, wherein the polypeptide ~~protein~~ solution has a pH ~~between~~ about 2.0 ~~and~~ to about 3.0;

increasing the pH of the polypeptide ~~protein~~ solution to between about 4 and 5 using 1N NaOH;

centrifuging the polypeptide ~~protein~~ solution and recovering precipitate-free supernatant; ~~and~~

adjusting the pH of the supernatant to ~~between~~ about pH 9 ~~and~~ to about 10.5 with 1N NaOH; and retaining the supernatant comprising isolated target polypeptide ~~protein at least about 10% more pure than the isolated target protein in aggregate form~~.

43. (Currently Amended) A method for isolating recombinant polypeptides comprising:

providing a non-buffered solution containing a stabilizing compound and sodium hydroxide ~~between~~ about 8 ~~and~~ to about 10 mM;

producing a polypeptide ~~protein~~ solution about 1 to about 4 mg polypeptide per ml by adding to the non-buffered denaturant free solution an insoluble recombinant polypeptide ~~between about 1 and 4 mg polypeptide per ml non-buffered solution~~, wherein the polypeptide ~~protein~~ solution has a pH ~~between~~ about 9 ~~and~~ to about 11.2;

lowering the pH of the polypeptide ~~protein~~ solution ~~between~~ to about 4 ~~and~~ to 5 using 1N NaOH;

centrifuging the polypeptide ~~protein~~ solution and recovering precipitate-free supernatant; ~~and~~

adjusting the pH of the supernatant to ~~between~~ pH of about 9 ~~and~~ to about 10.5 with 1N NaOH; and

retaining the supernatant comprising isolated target polypeptide ~~protein~~ at least about 10% more pure than the isolated target polypeptide ~~protein~~ in insoluble ~~aggregate~~ form.

44. (Currently Amended) A method for preparing bioactive recombinant polypeptide that has been denatured in a chaotrope-containing solution, comprising:

decreasing the concentration of the chaotropic agent in the chaotrope-containing solution by dialyzing the chaotrope-containing solution against a renaturing buffer of pH ~~between~~ of about 9 ~~and~~ to about ~~11.2~~ 10.5 and buffer concentration ~~between~~ of about 10 ~~and~~ to about 50 mM, wherein the renaturing buffer further contains a stabilizing compound~~;~~

~~chromatographically purifying the protein; and dialyzing the isolated protein against an aqueous stabilization buffer comprising a stabilizing compound.~~

45. (Original) The method of claim 44, wherein the stabilizing compound is a sugar or polyol.

46. (Currently Amended) The method of claim 44, wherein the stabilizing compound is a sugar ~~between~~ about 2 ~~and~~ to about 12 mM.

47. (Currently Amended) The method of claim 44, wherein the stabilizing compound is a polyol ~~between~~ about 5 ~~and~~ to about 100 mM.